PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

McLEISH, N., et al
BOULT WADE TENNANT
Verulam Gardens
70 Gray's Inn Road
London WC1X 8BT
GRANDE BRETAGNE

Mr McLeish
a 3/4/01
d/c 30/6/01
NB 3/4

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	30.03.2001
Applicant's or agent's file reference NAM/P57036/000	**REPLY DUE** 6/30/01 **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/17206	22/06/2000	02/07/1999

International Patent Classification (IPC) or both national classification and IPC

A61F2/06

Applicant

ENDOTEX INTERVENTIONAL SYSTEMS, INC.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☐	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☒	Certain document cited
VII	☒	Certain defects in the international application
VIII	☒	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 02/11/2001.

Name and mailing address of the international preliminary examining authority:
European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized offic r / Examiner
Fontenay, P

Formalities offic r (incl. extension of time limits)
Edel, M
Telephone No. +49 89 2399 2426

EXHIBIT "A"

I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".)*:

Description, pages:

1-12 as originally filed

Claims, No.:

1-23 as amended under Article 19

Drawings, sheets:

1/2,2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

EXHIBIT "A"

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

EXHIBIT "A"

R Item III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

III.1 The various definitions of the invention given in independent claims 1 and 11 referring to a stent are such that the claims as a whole are not concise, contrary to Article 6 PCT. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection. The claims should include the minimum necessary number of independent claims in any one category, Rule 6.1(a) PCT, with dependent claims as appropriate, Rule 6.4 PCT

In present case, considering that the claims 1 and 11 relate to the same subject-matter and only differ by the terminology employed, a single independent claim as to the device seems appropriate.

Should the applicant however consider that two independent claims for the device would be more adapted to the subject-matter to be protected, then he will be asked to justify his choice. In such a case, the inventions defined in the independent claims should also be linked by a single general inventive concept (Rule 13.1 PCT) i.e. the claims should be linked by a special technical feature in the sense of Rule 13.2 PCT.

III.2 The subject-matter of independent claims 1 and 11 is not clearly defined contrary to the requirements of Article 6 PCT.

The technical features of a "generally zig-zag pattern" or of a "generally arcuate shape" are not clear per se. The same applies to the feature of the connector extending "substantially parallel to the longitudinal axis". The attention of the applicant is here drawn to the Guidelines, PCT/GL/3, Chapter IV, § 4.5a.

A further lack of clarity of claim 1 results from the reference to the clockwise or counter-clockwise direction. It is namely not possible to derive from the wording of claim 1 what said directions are corresponding to.

EXHIBIT "A"

The feature of "a plurality of generally bat shaped cells" as it appears in claim 11 is too vague. Such a definition does not allow the reader to identify the claimed subject-matter. It is also not clear from the description what a bat shaped cell is corresponding to.

III.3 The claims should be clear as to their category. It is noted that the only technical feature of claim 4 refers to the use of the claimed stent. It is accordingly not clear which structural limitation as to the stent results from the proposed wording (see also the Guidelines, PCT/GL/3, Chapter III, § 4.1).

It is accordingly not presently possible to carry out the examination of the present application. However, in order to assist the applicant when filing possible amended claims following comments as to claim 1 are made.

III.4 Reference is made to the following documents:

D1: WO-A-9835634
D2: WO-A-9944543
D3: EP-A-806190

The documents D1, D2 and D3 were not cited in the international search report. Copies of the documents are appended hereto.

The subject-matter of claim 1 is not new in the sense of article 33(3) PCT.

D1 discloses a stent comprising a generally tubular body having a longitudinal axis and a circumference and adapted for introduction in a body lumen (see D1, page 1, lines 4-13). Said stent comprises a plurality of cylindrical bands formed in the tubular body, each band comprising a generally zig-zag pattern (4''', 5'''. 6''') comprising a series of sequential diagonal elements connected to one another and extending about the circumference (see D1, figure 6). In D1, the diagonal elements have a generally arcuate shape, all diagonal elements in each band being oriented in either a clockwise or counter-clockwise direction about the circumference. A plurality of longitudinal connectors (22''') extending between and connecting adjacent bands are also provided in D1. Each connector is also

EXHIBIT "A"

extending substantially parallel to the longitudinal axis (see figure 6; page 7, lines 9-26).

All the features of claim 1 as may presently be understood are known in combination from the prior art.

It is further noted that claim 1 is also anticipated by D2 and D3 (see D2, figure 1 and D3, figure 3).

Re Item VI Certain documents cited

Reference is made to the following document:

D4: WO-A-0028921:

VI.1 D4 claims a priority of 16.11.98 (before the date of the priority claimed for the present application) and has been published on 25.05.00 i.e. after the priority date and before the filing date of the present application. Since a copy of the priority document for the present application is presently not available, it is accordingly not possible at present, to state whether D4 is part of the prior art according to Rule 64.1 PCT or not.

The content of D4 (cf. D4, figure 2) is particularly relevant for the subject-matter of the invention as defined in the present claims, so that this aspect as to the priority may be essential in a later stage when deciding upon novelty and inventive step of the present invention.

VI.2 The attention of the applicant is also drawn to the fact that in a later regional stage before the EPO, documents D4 would be part of the prior art in the sense of Article 54(2) EPC (in combination with Article 89 EPC) in the case that the priority claimed for the present application would be found invalid. In the case that said priority would be found as validly claimed, D4 would then be part of the prior art in the sense of Article 54(3) EPC.

EXHIBIT "A"

Re Item VII Certain defects in the international application

VII.1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1, D2 and D3 is not mentioned in the description, nor are these documents identified therein.

VII.2 Independent claim should be drafted in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate.

VII.3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

VII.4 The general statement in the description, page 12 lines 20-23 suggesting that the extent of protection may be expanded in some vague way should be deleted (Article 6 PCT). The applicant may refer to the Guidelines, PCT/GL/3, Chapter III, § 4.3a.

VII.5 The application documents should be self-contained. The applicant should refer to the Guidelines PCT/GL/3, Chapter II, § 4.17. In present case, the wording "incorporated by reference" as it appears on page 9, lines 3 and 10 should be deleted.

Re Item VIII Certain observations on the international application

see comments under section III.

Comments:

The applicant may file possible amendments by way of replacement pages in the manner stipulated by Rule 66.8(a) PCT. In particular, fair copies of the amendments should be filed preferably in triplicate.

Moreover, the applicant's attention is drawn to the fact that, as a consequence of

EXHIBIT "A"

Rule 66.8(a) PCT the examiner is not permitted to carry out any amendments under the PCT procedure, however minor these may be.

In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

EXHIBIT "A"